

REMARKS

Claim 1 has been amended by incorporating the stability limitation of claim 12, which has been canceled. The present retinoid stabilization system does not require crystalline (i.e., solid) fatty acid. According to the present invention, the polymeric emulsifiers (*containing a hydrophilic backbone modified with hydrophobic groups*) serve the function of preventing water from entering the retinoid phase and vice-versa, thereby advantageously achieving retinoid stability of as high as at least about 70 days at 50°C, which is greater than that possible with a barrier according to Habib et al. A Rule 132 Declaration is enclosed in support of the present claims.

Additionally, claims 3, 4 and 10 have been canceled, without prejudice.

The Present Invention

The present invention is directed to stabilization of Retinoids. The unique system consisting of, as essential components, a *retinoid solubilized in a fluid oil*, in combination with a polymeric emulsifier selected from polymers containing a *hydrophilic backbone modified with hydrophobic groups*, and *polyhydric alcohol humectant*, enables greater Retinoid stability than previously possible. A Retinoid half-life as long as at least about 70 days at 50°C is advantageously achievable according to the present invention.

35 U.S.C. §112

The indefiniteness rejection has been rendered moot by cancellation of claims 3, 4 and 10, without prejudice.

Claims 1, 6-9 and 11 Are Not Obvious Under 35 USC § 103 Over Habif et al. (EP 832 643) in view of Simon (US 6,346,256)

According to the Office Action, Habif et al. disclose the stabilization of an unstable retinoid in oil-in-water emulsion for skin care compositions.; Exemplified is a composition comprising 3% butylene glycol-1,3 (humectant), stearyl alcohol (fluid oil alcohol), stearic acid (crystalline fatty acid), isostearyl palmitate (fluid oil), dimethicone (volatile silicone), linoleamide (retinoid booster) and 0.29% retinol.; The compositions of the invention preferably have a half-lifetime of from 20-45 days at 50°C.; Simon teaches Pemulen TR2 (a polymer containing a hydrophilic backbone modified with hydrophobic groups) as stabilizing oil-in-water emulsions. The Office Action concludes, that, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add Pemulen TR2 to the oil-in-water emulsions of Habif et al. because of the expectation of achieving a highly stable emulsion (emphasis added, distinguished below). Further according to the Office Action, while the reference does not teach the half-life of the retinoid in the composition of about 70 days at 50°C, the composition of the combined references must have these properties, since the combined references teach the composition of the instant invention, etc. Applicants respectfully traverse the rejection.

The Invention Is Directed to a Superior System for Stabilizing *Retinoids*

Habif stabilize retinoids in a different way than the present invention. Habif do not stabilize retinoids to as great a degree as the present invention.

See enclosed Rule 132 Declaration in support of the present claims. The present invention excludes crystalline, *solid*, barrier ingredient, rather achieving retinoid stability with the specified polymeric emulsifier system.

As established in the data presented in the Rule 132 Declaration, the Habif et al. system cannot achieve stability as great as the present invention, either as described or with addition of emulsifiers.

Claim 1 excludes the *crystal forming and* crystal sizing components, which is essential to the *solid, crystalline*, barrier component in the composition of Habif et al. See Habif et al. Claim 1. Compare Habif et al., page 4, lines 4-7 (stating that the barrier ingredient is **essential** to the emulsions of Habif); Claims 1 and 3; p. 3, lines 28-33. In fact, *Habif teach away from the present invention*, as Applicants are able to achieve retinoid stability in the absence of the *solid crystalline barrier* component. *Evidence of material difference is in Habif et al. itself, and is further illustrated with the accompanying Rule 132 Declaration.* Accordingly, Applicants respectfully submit that their composition is materially different from that of Habif and from Habif in combination with Simon (assuming there were motivation to combine the references, which Applicants submit there is not).

The Invention Is Directed to a Superior System for Stabilizing *Retinoids*

As previously established, Habif stabilize retinoids in a different way than the present invention. Habif do not stabilize retinoids to as great a degree as the present invention. See enclosed Rule 132 Declaration in support of the present claims. The present invention excludes crystalline, *solid*, barrier ingredient, rather achieving retinoid stability with the specified polymeric emulsifier system.

As established in the data presented in the Rule 132 Declaration, the Habif et al. system cannot achieve stability as great as the present invention, either as described or with addition of emulsifiers.

Claim 1 excludes the *crystal forming and* crystal sizing components, which is essential to the *solid, crystalline*, barrier component in the composition of Habif et al. See Habif et al. Claim 1. Compare Habif et al., page 4, lines 4-7 (stating that the barrier ingredient is **essential** to the emulsions of Habif); Claims 1 and 3; p. 3, lines 28-33. In fact, *Habif teach away from the present invention*, as Applicants are able to achieve retinoid stability in the absence of the *solid crystalline barrier* component. *Evidence of material difference is in Habif et al. itself, and is further illustrated with the accompanying Rule 132 Declaration.* Accordingly, Applicants respectfully submit that their composition is materially different from that of Habif and from Habif in combination with Simon (assuming there were motivation to combine the references, which Applicants submit there is not).

There Is No Motivation to Combine Habif et al. with Simon

Furthermore, there would be no motivation for one skilled in the art to look to Simon for stabilizing *retinoids* as Simon has nothing to do with retinoids. One skilled in the art with the goal of stabilizing retinoids would not be motivated to look to Simon, which discusses stabilizing emulsions.

The basic and novel characteristics of the present invention are set forth in the independent claim 1, as amended, as well as in the Specification.

The present invention is directed to a superior alternative system for stabilizing retinoids in the composition.

In view of the foregoing amendment and comments, applicants request the Examiner to now allow the claims.

Respectfully submitted,



Ellen Plotkin
Registration No. 36,636
Attorney for Applicant(s)

(201) 840-2253